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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,125

04/02/2004

Nabil L. Muhanna

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07/09/2008

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/817,125	<b>Applicant(s)</b> MUHANNA ET AL.	
	<b>Examiner</b> JAMES L. SWIGER	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-22, 25, 29 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15-22, 25, 29 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/2008 has been entered.

### ***Claim Objections***

Claim 38 is objected to because of the following informalities: Claim 38 improperly depending from claim 38. As such, claim 38 will not be treated further on the merits thereof. Appropriate correction is required.

Claim 42 objected to because of the following informalities: Claim 42 is depending from claim 23, which is a canceled claim. As such, claim 42 will not be treated further on the merits thereof. Appropriate correction is required.

Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 44 claims that a rod can accomodate turns of up to about 40 degrees from collinear with respect to the second rod. Thus the claim can be more than 40 degrees. Claim 43 from which it depends positively claims the range of 10-20 degrees, which means the total angle

cannot exceed 40 degrees. Thus claim 44 fails to properly further limit the subject matter of the previous claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 44 may provide an angle greater than 40 degrees. Page 15 of the specification, lines 15-17 claim that the conical surface may be between 10-20 degrees. If assuming that 20 and 20 from each side create the 40 degree angle, then claiming a range outside of 40 (i.e. up to about 40) is not support by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant means by stating that an entire range of motion between a first and second rod may be achieved without rotation of

either rod. An entire range of motion would include all motion in all directions and all degrees of freedom. It is unclear how you can have all motion when it is simultaneously being limited in some way.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 4-6, 8, 10-11, 13, 15-16, 17-19, 20-22, 25, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (U.S. Patent No. 5,910,142) in view of Ferree (US Patent 6,802,844).

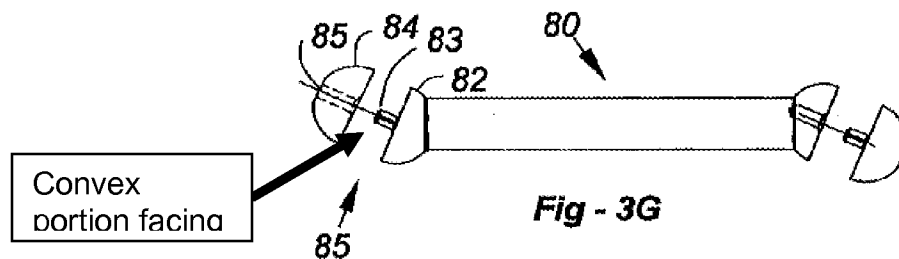
Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126), which may be considered concave. The rod also goes through the bore of the collet and

the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124). These threads are considered integral at least with the insertion portion of the yoke portion. The yoke portion is considered fixed relative to the threaded insertion portion (upper part), which may be considered a functional limitation of the structure. Considering the entire upper portion as a yoke, the individual 'posts' of the yoke are threaded on the inner surfaces and create a concave seat.

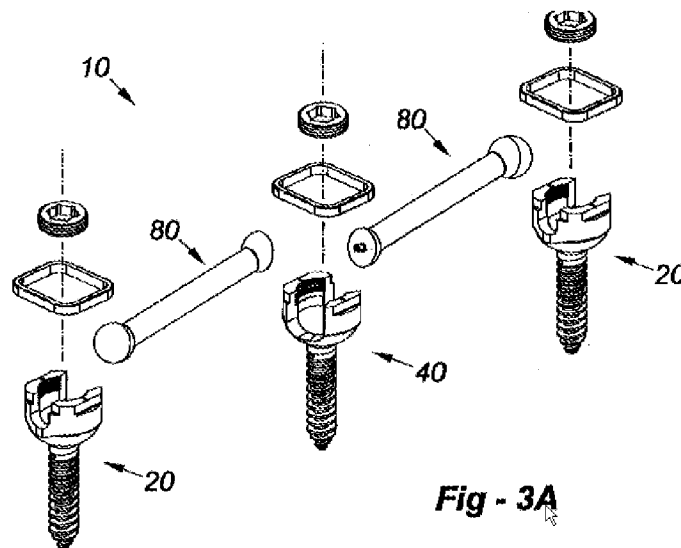
With regard to the threaded posts being fixed relative to the threaded portion, it is noted that the Tatar device comprises several parts, i.e. the yoke and insertion portion, which are rigidly secured together as a single unit when they are assembled. However, it would have been an obvious matter of design choice that the constituent parts are so combined as to constitute a unitary whole or structure, at least being fixed in a disassembled state. In re Larson, 144 USPQ 347 (CCPA 1965).

Tatar discloses the claimed invention except for at least a second end of the rod to have a spherical ball member, a rod having a second end with a convex surface that faces an inboard side (having a central recess) of a second end, multiple components (i.e. first, second, or third pedicle screws, first and second caps, multiple pedicle screws and rods with ends).

Ferree disclose a spinal apparatus having a rod with at least one bulbous end (Fig. 36), and an end with a convex end facing the inboard side of an end (see below)



Ferree also discloses multiple components (i.e. first, second, or third pedicle screws, first and second caps, multiple pedicle screws and rods with ends); see below.



These modifications help the device to better conform to the vertebrae and allow for various angles (see Col. 8, lines 36-39) of the components to better fit to the spine. See also Col. 2, lines 14-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least at least a second end of the rod to have a spherical ball member, a rod having a second end with a convex surface that faces an inboard side (having a central recess) of a second end, and multiple components to better arrange the assembly in use.

Tatar and Ferree disclose the claimed invention except for the end of the rod of having a tapered inboard side and a hemispherical outboard side to permit angulation. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the bulbous ends of the rods with such an angle, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of having additional movement to better orient the device during spinal surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142, and Ferree and in further view of Doubler et al. (U.S. PG-PUB 2005/0070899 A1). Tatar and Ferree disclose the claimed invention except for a crown having a cylindrical skirt and a radially inwardly projecting flange. Doubler et al. '899 discloses a crown with a cylindrical skirt and flange (see Figure X below) that enables the user to engage the outer spherical surface of the pedicle screw (par 0066) while this skirt rests on the inwardly projecting flange to more evenly distribute force throughout the connection (see bottom of par. 0075). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar and Ferree having at least the crown and skirt and inwardly projecting flange in view of Doubler et al. to better enable the surgeon to better secure the rods in the place after adjusting during the surgical procedure.

Claims 34-36, 40-41, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 and Ferree '844. Tatar '142 and Ferree '844 disclose the



claimed invention except for the spherical body being of various sizes. It is further noted that applicant is not clear as to what applicant is requiring in claim 44, as it is not supported by the specification, requiring a range of up to about 40 degrees. However, it would have been an obvious matter of design choice to have the spherical body of various sizes, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 and Ferree '844 and in further view of Sgier et al. (US Publication 2005/0171538). Tatar discloses the claimed invention except for a plurality of slots spaced about the surface of the ball collet in alternating fashion to connect with the bore. Sgier et al. disclose slots (6) that communicate with the surrounding area of the bore (par. 0019) to better fit within the cavity (par. 0012). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a ball collet with alternating slots in view of Sgier et al. to better secure the rod and collet within the bore.

Claims 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 and Ferree '844 and in further view of Sgier et al. Tatar '142 and Ferree '844 and Sgier et al. disclose the claimed invention except for the spherical body being of various sizes. It would have been an obvious matter of design choice to have the spherical body of various sizes, since such a modification would have involved a mere change in

the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tatar '142 and Sgier et al. '538 and Griss '268.

Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126), which may be considered concave. The rod also goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124). These threads are considered integral at least with the insertion portion of the yoke portion. The yoke portion is considered fixed relative to the threaded insertion portion (upper part), which may be considered a functional limitation of the structure. Considering the entire upper portion as a yoke, the individual 'posts' of the yoke are threaded on the inner surfaces and create a concave seat.

Tatar disclose the claimed invention except for a ball collet with a plurality of slots in alternating fashion. Tatar discloses the claimed invention except for a plurality of slots spaced about the surface of the ball collet in alternating fashion to connect with the bore. Sgier et al. disclose slots (6) that communicate with the surrounding area of the bore (par. 0019) to better fit within the cavity (par. 0012).

Tatar discloses the claimed invention except for the pedicle screw to be formed from titanium or an alloy thereof. Griss discloses within the scope of the invention the use of titanium or similar alloy (Col. 6, lines 53-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a ball collet with alternating slots or a material of titanium in view of the combination of Sgier et al. and Griss to better use the device and be associated with the body, as it would have improved sizability and biocompatibility when used in the surgical application.

Further Tatar '142 and Sgier et al. '538 and Griss '268 disclose the claimed invention except for the spherical body being of various sizes. It would have been an obvious matter of design choice to the construct the spherical body of various sizes, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-11, 13, 15-22, 25, 29 and 34-44 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3733

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731